

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Geena MALHORTA et al

Confirmation: 5437

Serial No.: 10/562,218

Group Art Unit: 3771

Filed: April 25, 2006

Examiner: DOUGLAS,
STEVEN O.

For: **PHARMACEUTICAL DISPENSING AID**

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Reconsideration of the rejections set forth in the Office Action of April 23, 2009, are respectfully requested. Of even date herewith is filed a petition for extension of time, together with the appropriate government fee.

Claims 1, 2 and 11-17, stand rejected under 35 U.S.C. 103 (a) as being unpatentable over Jordan (GB 2195544). The Office Action concedes that the Jordan reference "fails to disclose the plastic material as being at least partially or entirely polycarbonate".

Not only does the reference fail to teach that the plastic material is partially or totally polycarbonate, the Examiner also overlooks the additional limitations of claim 1 that the polycarbonate "does not having any coating on the interior surface thereof".

In addition, independent claim 14 includes the further limitation in a method of using polycarbonate in a canister of a metered dose inhaler, the step of "reducing or preventing the adhesion of the formulation to the interior surface of the canister".

Independent claim 15 has a similar recitation which also is not addressed by the deficiency of Jordan but omitted by the Examiner during the statement of the Jordan teachings.

Although the Examiner cites *In re Leshin*, 125 USPQ 416, for the proposition that it “has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice” here there is no teaching in Jordan, the general knowledge of those skilled in the art, or any other cited reference, that shows a polycarbonate, especially one devoid of any interior coating, which reduces or prevents the adhesion of the formulation to the interior surface of a canister of a metered dose inhaler (MDI) and therefore there is no teaching for any of independent claims 1, 14 or 15 of the claimed property possessed by the polycarbonate, but apparently only within the knowledge of the inventors of the present application.

With regard to the rejection of claim 13, applicants respectfully dispute the Examiner’s “Official Notice” as set forth in the rejection. Applicants are not merely claiming “injection molding and injection blow molding” but are specific to injection molding or injection blow molding a polycarbonate canister, “placing a pharmaceutical formulation in the canister, then securing a metering valve to the polycarbonate canister”. The Examiner has not even addressed these steps in the “Official Notice” section of the Office Action and therefore applicants respectfully dispute the Examiner’s “Official Notice” comments.

Furthermore, with regard to the Examiner’s comments regarding claims 14 and 15, the method as claimed is not “inherent” because to be “inherent” the device must inevitably perform as recited, i.e., there must be identity between the method as claimed and the prior art. Because the Examiner has not found identity (note the 35 U.S.C. 103 (a) rejection) the Examiner has conceded that claims 14 and 15 are novel and hence not “inherently” anticipated by the claimed invention. Now the Examiner has the burden of proving

obviousness, which under the *KSR* case and its progeny, the Examiner must act as a fact finder to show that formulation adhering to the canister interior is reduced or prevented by the claimed method. The Examiner has not even attempted to act as a fact finder for these teachings and thus, has failed to establish a prima facie case of obviousness for the claimed invention.

No other prior art discloses the use of polycarbonate in canisters for metered dose inhalers (MDI) to prevent adherence of the formulation to the interior walls of the canister. The Examiner has cited no teaching of any type whatsoever of anti-adherent properties for MDI's and especially none for polycarbonate materials. For all the foregoing reasons applicants respectfully submit that the Examiner has not established a prima facie case of obviousness as to claims 1, 2 and 11-17, under 35 U.S.C. 103 (a) and withdrawal of the rejection is therefore respectfully requested.

Reconsideration of the rejection of claim 6 under 35 U.S.C. 103 (a) as being unpatentable over Jordan, (discussed above) in view of Morris Jr. (U.S. Patent 4,105,142) is requested.

The deficiencies of Jordan have been addressed above.

Claim 6, dependent on independent claim 1, adds the additional limitations that "the canisters is provided with markings indicative of the number of doses the formulation remaining in the canister (emphasis added)".

The Examiner concedes that "the Jordan reference discloses a pharmaceutical dispenser, but fails to disclose markings indicative of the amount remaining in the canister (emphasis added)". While it is said that the Morris Jr. reference discloses another dispenser having markings 42 indicative of the amount of substance remaining in the dispensing container, such is not found within the teaching of Morris Jr. reference. Morris Jr., at column 3, lines 55-56, only states that "graduated markings 42" are found on dispensing container 12. However, if one reads the disclosure container 12 is neither an MDI nor are the markings

indicative of doses left in container 12. If the Examiner would read the Morris Jr. disclosure in context, it will be seen that dispensing container 12 is filled from holder 10 in order to measure out the dosage to be delivered. See column 4, lines 27-30, which states “in this position substance 11 will flow by the force of gravity from the holder 10 through the hollow adapter 20 into the dispensing container 12. The operator may observe the accumulation of substance 11 within the container 12 until the desired amount of substance has been gathered therein as shown by the graduated markings 42 (emphasis added)”. There is absolutely no teaching in the Morris Jr. disclosure of the limitation “to indicate the amount of substance remaining in the dispensing container” as specifically recited in claim 6. Accordingly, Morris Jr. also fails to supplement the Jordan reference in establishing a prima facie case of obviousness for the claimed invention. Withdrawal of the rejection are therefore respectfully requested.

Reconsideration and withdrawal of the rejection of claims 7-9 and 18 under 35 U.S.C. 103 (a) as being unpatentable over Jordan (discussed above) in view of Dickinson et al (U.S. Patent 6,737,044) is respectfully requested. Again it is admitted that the Jordan reference “fails to disclose the formulation of the pharmaceutical being one of salbutamol, ipratropium and budesonide, and a propellant”. Although Dickinson et al is alleged to disclose “another pharmaceutical dispenser including a formulation of the pharmaceutical being one of salbutamol, ipratropium and budesonide, and a propellant” the Examiner has provided no reason why one having ordinary skill in art at the time the invention was made would substitute the pharmaceutical formulation of Dickinson et al. for the formulation of Jordan because, in the claimed invention, it is required that the canister be formed of a polycarbonate without any interior coating, and the reason why polycarbonate is utilized with this pharmaceutical formulation is to reduce or eliminate adhesion of the formulation to the interior walls of the polycarbonate canister. Dickinson does not teach any of such limitations and therefore it would not have been obvious to make the proposed combination suggested in

the Office Action and, even if the combination was made, it still would not result in the claimed invention. For all the foregoing reasons withdrawal of all rejections and passage of the application to issue are respectfully requested.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1437, under Order No. 8693.014.US0000.

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Respectfully submitted,



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